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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/893,324 | 06/27/2001 | Laszlo Prokai | 1540/139 | 2061 |
| 2101 | 7590 | 08/11/2004 | EXAMINER | |
| BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618 | | | QAZI, SABIHA NAIM | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 09/893,324 | Applicant(s) PROKAI ET AL. | |
| | Examiner Sabiha Qazi | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2004.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1 and 5-9 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/04 has been entered.

Amendments are entered. Claims 1 and 5-9 are pending. No claim is allowed.

The declaration was fully considered but the arguments are not found persuasive. Rejection under 35 U.S.C. 112, first paragraph is withdrawn. Rejection over Simpkins reference is maintained. The argument that the long chain saturated alkyl, long chain unsaturated alkyl, or long chain cycloalkyl groups show unexpected and surprising research results is not supported with any substantial data. It is also not clear what Applicants mean by "long chain" because claim 6 is drawn to C3 alkyl, which is not a long chain alkyl. A clarification is requested. The reference US '601 discloses several alkyl ether compounds. Examiner expects clear and well-documented data to back up the arguments and claims. Since the pharmaceutical compositions of the claimed compounds are known, Applicants have a burden to prove that their invention is new and is not disclosed or taught by the prior art. For the same reasons, the rejection under 103 over US '601 is maintained. Furthermore, new anticipation rejections are being made as follows.

Presently claimed invention of claim 1 and 5-9 drawn to a pharmaceutical formulations of estrogen (A ring is aromatic), OH at 3-position and having long chain unsaturated or saturated alkyl ether or cycloalkyl group at 17 position such as 1, 3, 5(10) triene-3-ol-17-alkyl ether estradiols.

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The reference Gridley et al. cited in line 18-19 on page 1 of the specification is incomplete as the Journal name is missing. Applicant should amend the specification for complete information about the reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply:

It is unclear what is intended by “long chain alkyl group”?. Examiner notes, that claim 6 recites a member with $n=3$. Is this a long chain unsaturated alkyl group?.

The term “includes” in claim 1 is open ended. It should be deleted.

Claim Rejections - 35 USC § 102

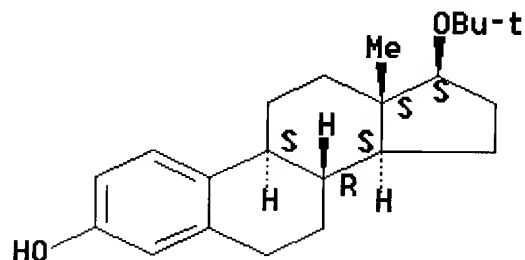
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by AN 1976:554233 HCAPLUS, DN 85:154233 (Abstract of Byulleten Eksperimental'noi Biologii i Meditsiny; “SHCHEDRINA et al.”).

SHCHEDRINA et al. discloses a butoxyestra compound having high affinities for the estradiol-binding system. See compound of RN 38781-59-8 HCAPLUS.

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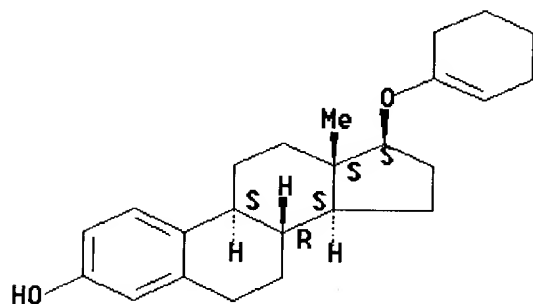
Absolute stereochemistry.



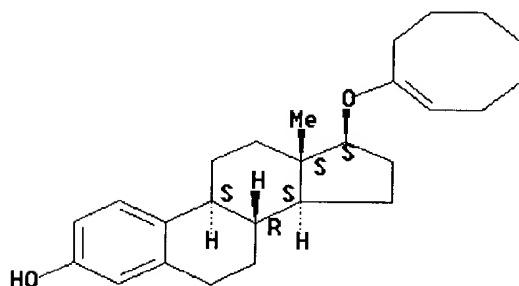
38781-59-8 HCAPLUS

Claims 1 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by AN 1973:106316 HCAPLUS, DN 78:106316 (Abstract of "Journal of Medicinal Chemistry"; "GARDI et al.").

GARDI et al. discloses the cycloalkyl ethers at 17 position of estratriens. See compounds of RN 13885-34-2 HCAPLUS, RN 41622-69-9 HCAPLUS, and RN 41622-84-8 HCAPLUS.



13885-34-2 HCAPLUS

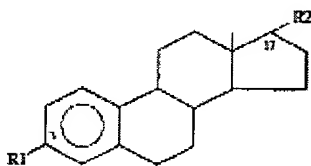


41622-69-9 HCAPLUS

Examiner would like to emphasize that the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

Claim Rejections - 35 USC § 103

Claims 1 and 5-9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Simpkins et al. (US 5,554,601). Simpkins et al. teach estra-17 substituted alkyl ether for neuroprotection and method for treating neurodegenerative diseases including Alzheimer's disease, which embraces Applicant's claimed invention. See the entire document especially lines 11-54, col. 3; lines 1-42, col. 4; examples and claims especially claim 4.



Instant claims are drawn to 17-substituted alkyl ether at D ring in a compound having aromatic ring A.

Instant claims differ from the reference by reciting specific species and/or a more limited subgenus than the reference. See formula in col. 4 and Figs 9A and 9B on sheets 9 and 10 where various substituents at R1 and/or R2 are listed, which includes valerate, stearate, and benzyl ether. Arguments that presently claimed invention disclaims methyl ether and ethyl ether at R 17 position, compounds are still considered obvious due to the reason cited above. Note, that US '601 teaches that "estrogen compound" is defined as any structure described in the 11th edition of "steroids" from Sternaloids Inc. and is incorporated as a reference. See lines 50-67 in col. 4. In present application same reference is incorporated. Even though some compounds are disclaimed, other steroids are considered obvious.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Thursday, August 5, 2004